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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/634,368   | 08/06/2003  | Kenneth Stewart      | STEWART             | 6917             |
| 7590   | 05/18/2007  | EXAMINER             |                     |                  |
| Evelyn M. Sommer<br>Suite 825<br>250 Park Avenue<br>New York, NY 10022 |             | SHAFFER, RICHARD R   |                     |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 3733                 |                     |                  |
|  |             | MAIL DATE            |                     | DELIVERY MODE    |
|  |             | 05/18/2007           |                     | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication. — — —

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/634,368             | STEWART, KENNETH    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Richard R. Shaffer     | 3733                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 February 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-22 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 13-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-12,21 and 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-12, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 has the new limitation of the bone instrumentation cover or shield "capable of being permanently" installed in bone. Applicant's cover is not what is installed in the bone as clearly stated later in the claim in which it covers the instrumentation, which is inserted in bone. The cover remains outside of the bone and is not inserted in the bone and especially not "permanently installed" within bone.

Claim 22 states the limitation, "at least one member selected from the group consisting of GoreTex, Dacron, and polyurethane." Applicant's disclosure states that the cover or shield "is made of proven, medically safe material, such as GoreTex™, Dacron™, polyurethane, or any other safe implantable material." Nowhere does it state that such may be used in combination with other materials, or even combinations of the stated materials. Therefore the claim is directed towards new matter. Further, applicant must properly include the trademark symbols where appropriate.

All dependent claims have been rejected for being dependent upon an unsupported base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by McIntyre (US Patent 3,746,066).

McIntyre discloses (**Figures 1-3**) a cover/shield (1) comprising: a flexible, hollow cap/casing pouch; a cinch ring portion (top of **Figure 2** extending down to 16) to close a box-like aperture by drawstrings through a tubular section of the cinch ring portion; and the cinch ring also having openings (16) to allow sutures (5a, 5b) to pass through to allow the cap/casing to tighten vertically toward the cinch ring.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre.

McIntyre discloses all of the claimed limitations except is silent as to the cap/casing being made of GoreTex™, Dacron™, or polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of McIntyre with the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Richard Shaffer*

Richard Shaffer  
May 12<sup>th</sup>, 2007

*[Signature]*  
EDUARDO G. ROBERT  
SUPERVISORY PATENT EXAMINER

|                                   |  |  |                         |   |  |
|-----------------------------------|--|--|-------------------------|---|--|
| <b>Notice of References Cited</b> |  |  | Application/Control No. | Applicant(s)/Patent Under Reexamination |  |
|                                   |  |  | 10/634,368              | STEWART, KENNETH                        |  |
| Examiner<br>Richard R. Shaffer    |  |  | Art Unit<br>3733        | Page 1 of 2                             |  |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name                    | Classification |
|---|---|--|-----------------|-------------------------|----------------|
| * | A | US-403,928 A                                     | 05-1889         | Emeric                  | 383/6          |
| * | B | US-467,129 A                                     | 01-1892         | Cussen                  | 383/75         |
| * | C | US-2,552,443 A                                   | 05-1951         | JEANNE MOLINARI         | 224/601        |
| * | D | US-3,746,066 A                                   | 07-1973         | McIntyre, Mary Barbara  | 150/107        |
| * | E | US-4,815,640 A                                   | 03-1989         | Johnson, Rodney N.      | 224/601        |
| * | F | US-5,050,999 A                                   | 09-1991         | Van Loon, III, James C. | 383/76         |
| * | G | US-5,195,828 A                                   | 03-1993         | Bush-Rodriquez, Jeffrey | 383/4          |
| * | H | US-5,207,508 A                                   | 05-1993         | Koutsis, Jr., Philip    | 383/4          |
| * | I | US-5,411,165 A                                   | 05-1995         | Ellis, Thomas J.        | 220/495.08     |
| * | J | US-5,518,313 A                                   | 05-1996         | McAdam, Christine A.    | 383/4          |
| * | K | US-5,653,337 A                                   | 08-1997         | Cirigliano, Charles F.  | 206/373        |
| * | L | US-D453,620 S                                    | 02-2002         | Vazquez, Maximino       | D3/244         |
| * | M | US-D458,746 S                                    | 06-2002         | Vazquez, Maximino       | D3/244         |

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**NON-PATENT DOCUMENTS**

|   |   |   |
|---|---|---|
| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|   | U |   |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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|-----------------------------------|--|--|---------------------------------------|--|-------------|
| <b>Notice of References Cited</b> |  |  | Application/Control No.<br>10/634,368 | Applicant(s)/Patent Under<br>Reexamination<br>STEWART, KENNETH |             |
|                                   |  |  | Examiner<br>Richard R. Shaffer        | Art Unit<br>3733   | Page 2 of 2 |

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| * | A | US-6,419,135 B1                                  | 07-2002         | Sali, Kasper B.   | 224/610        |
| * | B | US-D460,616 S                                    | 07-2002         | Vazquez, Maximino | D3/244         |
| * | C | US-6,435,391 B1                                  | 08-2002         | Vazquez, Maximino | 224/656        |
| * | D | US-6,543,658 B2                                  | 04-2003         | Trevino, Jose     | 224/153        |
| * | E | US-D485,433 S                                    | 01-2004         | Vazquez, Maximino | D3/244         |
| * | F | US-D488,297 S                                    | 04-2004         | Vazquez, Maximino | D3/244         |
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|   | H | US-  |                 |                   |                |
|   | I | US-  |                 |                   |                |
|   | J | US-  |                 |                   |                |
|   | K | US-  |                 |                   |                |
|   | L | US-  |                 |                   |                |
|   | M | US-  |                 |                   |                |

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